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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,386	12/02/2003	Samuel J. Danishefsky	2003080-0143 (SK-744-CON9	5603

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EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,386	DANISHEFSKY ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 81-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 81-95 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 02 December 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 81-95 are pending in this application.

Claims 1-80 are cancelled.

Claim Rejections - 35 USC ∋ 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 81-95, are rejected under 35 U.S.C. 103(a) as being unpatentable over Bollag et al., Cancer Res., Vol. 55 (1995), pages 2325-2333.

Applicant claims compositions of epothilone B and methods of use for treating cancer or tumors particularly multi-drug-resistant cells. In preferred embodiments, the Composition is emulsion or aqueous suspension. Applicants also claim variable effective amounts of the epothilone, such as, from about 0.001 to about 0.06 mg/kg of body weight, and the frequency of administering the effective dose.

Determination of the scope and content of the prior art (MPEP ∋2141.01)

Bollag et al., teach epothilones A (R is H) and B (R is methyl), their compositions as oily residue (column 2, page 2326) and methods of use for treating cancer or tumor and particularly multiple drug-resistant cells. See column 2, page 2331. Bollag et al., also teach the method of use of epothilones in combination with taxol (a cytotoxic agent). See column 2, page 2328 to column 1, page 2330. Bollag et al., further compare epothilones A and B with Taxol, a known cytotoxic compound widely use as anticancer and antitumor. Bollag et al., concluded that the epothilones have improved solubility profile and therapeutic index. See column 1, page 2333.

Ascertainment of the difference between the prior art and the claims (MPEP ∋2141.02)

The difference between the instant invention and that of Bollag et al., is that applicant is claiming effective amounts of the epothilones from about 0.001 to about 0.06 mg/kg of body weight, and frequency of administration of the effective dose to a subject.

Finding of prima facie obviousness---rational and motivation (MPEP ∋2142.2413)

Bollag et al., teach the EC_{50} values of the epothilones for treatment, mitotic arrest and toxicity, in multiple drug resistance (MDR) and parental cells. See table 3. Therefore, claiming variable effective amounts of the epothilones, and administration of the effective dose to a subject multiple times is not in and of itself patentable over the prior art of Bollag et al. Administration of effective amount of a drug and its frequency, in the treatment of cancer is well known in the art of medicine.

The instant invention is prima facie obvious from the teaching(s) of Bollag et al. Having known the utility of the compound, one of ordinary skill in the art would have determine their effective therapeutic doses and frequency of administration without undue experimentation. The motivation is in the expectation that the epothilones composition would be effective for the treatment of cancer and/or tumor given the results of the comparative study between taxol and epothilones performed by Bollag et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 81-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-29 of U.S. Patent Application No. 10/695,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because in US '582 composition comprising any epothilone, while in the instant application the composition comprises only epothilone B.

Claims 81-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,828,340 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because in US '340 composition comprising specific different epothilones, while in the instant application the composition comprises only epothilone B.

Claims 81-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,849,651 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because in US '651 composition comprising a specific different epothilone, while in the instant application the composition comprises only epothilone B.

Relevant Prior Art

Hofle et al., WO 93/10121, teach epothilone A and B, and their pharmaceutical compositions (medicaments) as having cytotoxic and immunosuppressive activities.

Specification

The specification has holes punched through the top margin prior to its photocopy duplication. Therefore, several pages have incomplete or missing words in the first line. For example, see pages 19, 26, 29-30. The numerical pagination of some pages is not complete. For example, see pages 26, 29.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

TAOFIQ SOLOLA
PRIMARY EXAMINER

1626

August 18, 2005